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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
07/431,533	11/03/89	MORTON	D P318462

18M1/0115

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EXAMINER	
DAVIS, M	
ART UNIT	**PAPER NUMBER**
1806	52

DATE MAILED: 01/15/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 10/4/96

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 19, 62-79 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☒ Claim(s) 19, 62-79 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

– SEE OFFICE ACTION ON THE FOLLOWING PAGES –

★ U.S. GPO: 1996-410

Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous office action has been withdrawn pursuant to 37 CFR 1.129(a). Applicant's amendment filed on 10/04/96 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant adds new claims 66-79 which are related to claims 19, and 62-65, and are not new matter. Accordingly, claims 19, 62-65, and 66-79 are being examined.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, NEW REJECTION

Claim 72 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for enhancing in a subject the production of antibodies against UTAA following administering free UTAA to said subject, does not reasonably provide enablement for said enhancement of exactly 2-to 5-fold. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Claim 72 is drawn to a method for enhancing by 2-to 5-fold in a subject the production of antibodies against UTAA comprising administering free UTAA into said subject. The specification however only has support for enhancing by 2-to 5-fold the production of antibodies against UTAA in melanoma patients, following administering irradiated tumor cells having UTAA on

their cell surface into said subjects. The specification does not disclose the enhancement by 2-to 5-fold of the production of antibodies against UTAA in melanoma patients, following administering free UTAA into said subject. It is unpredictable whether injection of free UTAA into a subject who already has prior anti-UTAA antibodies would further increase the anti-UTAA titer by exactly 2-to 5-fold. The 2-to 5-fold enhancement of anti-UTAA titer following administering irradiated tumor cells having UTAA on their cell surface could not be extrapolated to the results from the administration of free UTAA because determinants on the injected irradiated tumor cells other than UTAA could act as an adjuvant or as a helper determinant and further increase the immunogenic response toward UTAA. Mitchison, N.A., 1970, Transplantation Proceedings, 2(1): 92-103, teach that introducing a new immunological determinants onto tumor cells could increase the immune response toward the tumor specific antigen of said tumor cells (p.96).

In the absence of such a teaching of the exact enhancement of the production of antibodies against UTAA in melanoma patients, following administering free UTAA into said subjects, one of skill in the art would be forced into undue experimentation in order to repeat the claimed method as broadly as claimed.

REJECTION UNDER 35 USC 102

Rejection under 35 USC 102(b) of claim 62 pertaining to anticipation by Real et al., US 4,562,160, remains for reasons already of record in paper No.47 and 41, and for reasons as follows:

Applicant adds new claims which are dependent on claim 62 and which recite properties of UTAA.

Rejection of claim 62 remains because by itself, claim 62 still reads on the Real's antigen. It is advised that the properties of UTAA which distinguish it from Real's antigen should be incorporated into claim 62.

REJECTION UNDER 35 USC 102/103

Rejection under 35 USC 102(b)/103 of claims 19, 62, 65, 67-68, 71, 73-79, pertaining to anticipation by Euhus, R. et al. 1988, remains for reasons already of record in paper No.47 and 41, and for reasons as follows:

Applicant argues that Euhus abstract is not enabling because key conditions such as the proper pH or ionic strength under which isolation was conducted are missing, as are the migration distance or retention times for gel or column purification.

Rejection of claims 19, 62, 65, 67-68, 71, 73-79 remains. Euhus cites that UTAA is purified by dye ligand and gel filtration, DEAE anion exchange chromatography or 4.5% polyethylene glycol precipitation. Information on the proper pH or ionic strength for DEAE anion exchange column is not necessary because it is well known in the art that a NaCl salt gradient

could be used for elution of proteins from DEAE anion exchange column, rather than elution by a fixed ionic strength (Pharmacia Fine Chemicals, 1980, Ion exchange chromatography, pp. 43-47). Similarly, information on the migration distance or retention times for gel filtration purification is not necessary because the retention times for gel filtration could be obtained from standard proteins with various molecular masses. The information on molecular mass of UTAA by Euhus as 620 KD provides an estimate retention time for UTAA by deducing the migration of 620 KD from the migration of standard proteins.

Claims 19, 65 are rejected because claims 19, 65 are drawn to a method comprising administering, in a subject, free UTAA which is made obvious by Euhus who recites the use of isolated UTAA for the immunoprognosis of human melanoma.

Claims 67-68, 71 are rejected because they are drawn to the inherent properties of UTAA which is made obvious by Euhus who isolates UTAA.

Claims 73-79 are rejected because they are drawn a pharmaceutical composition comprising UTAA, and thus read on UTAA in a carrier, i.e. buffer. The language pharmaceutical composition therefore is not given any patentable weight in applying prior art. Various concentrations of UTAA in a buffer of claims 74-79 are made obvious by Euhus because once UTAA is purified, it could be diluted in buffer, or concentrated to various concentrations.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Minh-Tam B. Davis whose telephone number is (703) 305-2008. The examiner can normally be reached on Monday-Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached on (703) 308-2731. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0916.

Minh-Tam B. Davis

December 30, 1996

LILA FEISEE
SUPERVISORY PATENT EXAMINER
GROUP 1800